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Guidelines for Application of Sterilization-used Packaging Materials in Chinese Healthcare Institutions

Compiling Group for association standard Guidelines for Application of Sterilization-used Packaging Materials in Healthcare Institutions

To refine the specific requirements for the use of sterilization-used packaging materials in healthcare institutions as stipulated by the mandatory national health industry standard *Three Standards for Hospital Central Sterile Supply Department* (WS 310) and to address the common gaps in understanding among hospital procurement departments regarding the product performance testing/usage requirements of sterilization-used packaging materials, the China Health Inspection Association has initiated the development of the association standard *Guidelines for Application of Sterilization-used Packaging Materials in Chinese Healthcare Institutions* based on expert application and project approval. This association standard aims to guide healthcare institutions at all levels in correctly selecting and standardizing the use of sterilization-used packaging materials, effectively eliminating medical safety hazards caused by unqualified materials, enhancing the safety of sterile medical devices, and ensuring patient safety.

1 Terms and Definitions of Sterilization-used Packaging Materials

Sterilization-used packaging materials provided by healthcare institutions for reusable medical devices, instruments, and items include medical textiles, medical non-woven fabrics, medical paper-plastic composites, medical polyethylene (PE) composites, medical paper/paper bags, medical crepe paper, and medical rigid sterilization containers.

1.1 Medical Textile

A packaging material made from long-filament polyester fibers and antistatic carbon fiber fabrics; reusable for steam sterilization.

1.2 Medical Non-woven Fabric

A disposable packaging material made from polypropylene via composite processes such as spunbond and meltblown; commonly used for steam sterilization, ethylene oxide (EO) sterilization, and low-temperature steam formaldehyde (LTSF) sterilization.

1.3 Medical Paper-Plastic Composite

A disposable preformed sterile barrier system consisting of breathable materials such as medical paper and composite films, e.g., medical paper-plastic composite coils and bags; commonly used for steam sterilization, EO sterilization, and LTSF sterilization.

1.4 Medical Polyethylene (PE) Composite

A disposable preformed sterile barrier system consisting of 100% high-density PE and composite films, e.g., medical PE sterilization coils and bags; commonly used for vaporized hydrogen peroxide (VHP) sterilization.

1.5 Medical Paper Bag

A disposable preformed sterile barrier system bonded by breathable materials such as medical paper; commonly used for steam sterilization.

1.6 Medical Crepe Paper

A disposable packaging material made from wrinkled medical paper to improve softness; commonly used for steam sterilization.

1.7 Medical Rigid Sterilization Container

A reusable rigid sterilization container consisting of a lid, container body or base, instrument basket, handle, sterilization indicator card slot, gasket, and pathway for sterilizing agent (valves or filter components); functioned as a sterile barrier system for device sterilization, storage, and transport; commonly used for steam sterilization, EO sterilization, VHP

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sterilization, LTSF sterilization, etc.

2 Management Requirements for Sterilization-Used Packaging Materials in Healthcare Institutions

2.1 Healthcare institutions shall establish a quality control management system for sterilization-used packaging materials and define the responsibilities of relevant departments.

2.2 Healthcare institutions shall establish a quality feedback mechanism; any product quality issues discovered shall be promptly reported to and handled with the supplier.

2.3 Healthcare institutions shall select qualified sterilization-used packaging materials according to this standard, based on the characteristics of reusable medical devices, instruments, and items, applicable sterilization methods, and the management requirements of the Chinese standard WS 310.1, and shall use them according to the product instructions. When adopting new packaging materials or new packaging methods, biological monitoring shall be performed according to the Chinese standard WS 310.3. Use is permitted only after passing monitoring, and the sterilized packaging materials/methods shall meet requirements for package integrity and closure integrity.

2.4 Before procurement, healthcare institutions shall organize relevant departments, such as the hospital infection management department and the central sterile supply department, to conduct quality review and evaluation, and verify the following product documentation:

2.4.1 Business licenses of the manufacturer and/or supplier (or commissioning manufacturer).

2.4.2 Valid sales authorization letter from the manufacturer within the authorization period; the content of the authorization letter shall match the products sold.

2.4.3 A test report confirming that the manufacturer's production facility has a 100000-level cleanliness or more.

2.4.4 A list of laboratory equipment and supporting documents meeting requirements for release testing and batch testing from the manufacturer.

2.4.5 Performance test reports.

2.4.6 Labeling and instructions for use.

2.4.7 The materials with external chemical indicators shall provide a disinfection product hygiene safety evaluation report and filing certificate.

2.4.8 Quality system certificates, including ISO 13485 or ISO 9001, may be provided.

2.4.9 A clinical usage report from healthcare institutions may be provided.

3 Test Report Requirements for Sterilization-Used Packaging Materials

3.1 Requirements for Performance Testing

3.1.1 Performance test reports shall be provided in accordance with the Chinese standard WS/T 10009 or YY/T 0681.

3.1.2 Performance test reports shall have CMA and/or CNAS marks.

3.1.3 Changes affecting the sterile barrier system of sterilization-used packaging materials require new performance test reports according to the Chinese standard GB/T 19633.1.

3.1.4 Corresponding performance test reports shall be provided according to the product model/characteristics (e.g., different basis weight materials, combination bags, double-layer composite disposable packaging, or other structural forms). Reusable medical textile shall provide performance test reports for the maximum allowed processing cycles as per instructions.

3.1.5 Biological monitoring reports shall be provided for the first-time use of sterilization-used packaging materials according to the Chinese standard WS 310.3.

3.2 Requirements for Performance Test Report

3.2.1 Microbial barrier performance test report: The test shall be performed according to the Chinese standard WS/T 10009 or YY/T 0681.10.

3.2.2 Shelf life and sterile validity period test report: Accelerated aging tests shall be performed according to the Chinese standard WS/T 10009 or YY/T 0681.1; the real-time aging test method is recommended for determining the sterile validity period.

3.2.3 Biocompatibility and toxicology test report:

In vitro cytotoxicity, skin irritation, and skin sensitization tests shall be performed according to the Chinese standards GB/T 16886.5 and GB/T 16886.10.

3.2.4 Physicochemical analysis reports

a) Medical textile shall provide test reports for physical performance indicators including average mass, drapability, dry and wet breaking strength in warp and weft directions, dry and wet tearing strength in warp and weft directions, dry and wet bursting strength, air permeability, and water resistance according to the Chinese standard YY/T 0698.2, as well as test reports for chemical performance indicators including color fastness, average mass, pH, sulfate content, chloride content, fluorescence brightness, number of fluorescent spots, and drape coefficient.

b) Medical non-woven fabric shall provide test reports for physical performance indicators including internal tear resistance, bursting strength, wet bursting strength, elongation at break, tensile strength, wet tensile strength, and water resistance according to the Chinese standard YY/T 0698.2, as well as test reports for chemical performance indicators including color fastness, average mass, pH, sulfate content, chloride content, fluorescence brightness, number of fluorescent spots, and drape coefficient.

c) Medical paper-plastic composite and PE composite should include test reports on raw material performance, which shall be provided by the raw material suppliers, e.g., plastic film materials shall meet the Chinese standard YY/T 0698.5, breathable materials such as medical paper shall meet the standard YY/T 0698.3, and non-woven fabric used in PE composite shall meet the standard YY/T 0698.9.

d) Medical rigid sterilization containers shall provide test reports for indicators including shape and dimensions, lid or lid locking device, handles, stacking capability, sterilizing agent inlet, and markings according to the Chinese standard YY/T 0698.8.

3.2.5 Adaptation test report for preforming and sealing processes: Confirmation and validation of preforming and sealability for medical paper-plastic composite and PE composite shall be performed according to the Chinese standard YY/T 0681.11 or YY/T 0681.4.

3.2.6 Adaptation test report for intended sterilization processes: Sterilizing agent penetration performance test reports shall be provided based on the applicable sterilization methods for the packaging materials according to the Chinese standard WS/T 10009.

3.2.7 Medical paper-plastic composite and PE composite with external chemical indicators: These materials shall comply with disinfection product hygiene safety evaluation management requirements and be tested/evaluated according to inspection items specified in Appendix F of the Chinese standard WS 628 (see Table 1).

3.2.8 Medical textile and non-woven fabric shall

Table 1 Inspection Items for Sterilization-used Packaging Materials with External Chemical Indicators

Inspection Item	Material Type	
	Breathable Material	Non-breathable Material
Sterile validity period test	+	+
Mass determination	+	+
Sterilizing agent penetration performance test	+	+
Effect of sterilization on packaging markings[a]	+	+
Microbial barrier test for breathable materials	+	−
Permeability test for non-breathable packaging materials	−	+
Sterilizing agent residue determination[b]	±	±
Packaging material validity period test[c]	+	+

Note: "+" indicates mandatory item; "−" indicates not required; "±" indicates optional.

a) Corresponding penetration tests for each sterilizing agent shall be performed separately for markings indicating multiple sterilization methods.

b) This test is not required for sterilization using physical agents.

c) Upon reaching the validity period labeled on the instructions, tests for sterile validity period verification, the effect of sterilizing agent on marking color change, and microbial barrier test for breathable packaging materials shall be conducted.

provide test reports for linting in the dry state.

3.2.9 Medical paper-plastic composite and PE composite shall provide test reports for clean peel.

4 Labeling Requirements for Sterilization-Used Packaging Materials

4.1 Requirements for Product Instructions

4.1.1 The product instructions shall include the product name, model, specifications, product standard, material composition, applicable sterilization methods, service life, storage conditions, usage precautions, manufacturer name, manufacturer address, and contact. For commissioned production, the name and production address of the commissioned company shall also be indicated.

4.1.2 Medical paper-plastic composite and PE composite shall provide data on sealing conditions (e.g., range for heat-seal temperature, pressure, and time) and methods for aseptic opening, respectively.

4.1.3 Medical rigid sterilization container shall provide instructions for use, cleaning procedures, performance inspection methods, criteria for continued use, requirements for accessory disassembly/assembly, service life of containers and gaskets, and sterilization parameters.

4.1.4 Medical textile shall provide cleaning methods, including detergent type, cleaning/disinfection parameters, etc., and performance inspection methods.

4.2 Requirements for Product Packaging Labels

4.2.1 The product packaging label shall indicate product name, model, specifications, quantity, production date, and validity period or batch No. and service life, scope of application, storage conditions, warnings, precautions, manufacturer name, manufacturer address, and contact.

4.2.2 Disposable or reusable shall be indicated.

4.2.3 Labels for medical paper-plastic composite and PE composite with external chemical indicators shall comply with the Chinese standard GB 38598.

5 Storage Requirements for Sterilization-Used Packaging Materials Upon Receipt

5.1 Inspection Requirements Upon Receipt of Sterilization-Used Packaging Materials

5.1.1 Physicochemical analysis report for the batch.

5.1.2 Product delivery order and batch certificate of compliance.

5.1.3 Products with damaged, damp, or stained outer packaging shall be rejected.

5.1.4 Product packaging labels as well as name, specifications/model, and batch No. on the outer packaging shall match the information on the batch test report.

5.1.5 The validity period shall meet the usage requirements of the healthcare institution.

5.2 Storage Requirements for Sterilization-Used Packaging Materials

5.2.1 Storage areas shall be clean, dry, well-ventilated, and protected from direct sunlight. The storage requirements for indoor temperature and humidity should preferably be met as specified in the product instructions.

5.2.2 Products shall be stored classified on dedicated shelves/racks, labeled, with intact packaging. Products shall be used within the validity period and followed by the first-in-first-out principle.

5.2.3 Non-conforming products shall be marked with warning signs and retained separately from conforming products.

6 Application and Precautions for Sterilization-Used Packaging Materials

6.1 Disposable Sterilization-used Packaging Materials

6.1.1 The disposable sterilization-used packaging materials shall be used within the validity period and shall not be reused.

6.1.2 The materials selected shall match the sterilization method (steam sterilization, VHP sterilization, EO sterilization, or LTSF sterilization). Specifications/model shall suit the weight and volume of the instruments, ensuring the integrity of the sealed/closed package.

6.1.3 The materials under adequate light shall be inspected before use; the materials shall be free from holes, cracks, tears, creases, or other defects that impair performance.

6.1.4 For medical paper-plastic composite and PE

composite with external chemical indicators, printed indicator marks shall be uniform and without migration or bleeding; color before and after sterilization shall match the product instructions.

6.1.5 Sealing parameter ranges for medical sealers shall be set according to the product instructions. For materials sealed manually using adhesives (e.g., paper bags), ensure a continuous seal covering the specified width.

6.1.6 Medical paper-plastic composite is suitable for packaging small, lightweight instruments. Each bag shall have at least one chemical indicator block corresponding to the sterilization method. External labels shall be attached to the plastic side; ensure aseptic opening after sterilization. Seal width shall be ≥6 mm; instruments inside shall be ≥2.5 cm from one side of the seal of the bag.

6.1.7 If the color change of the internal chemical indicator can be directly observed through the packaging material, it is not necessary to use an external chemical indicator.

6.1.8 External chemical indicators on packaging materials are process indicators; color change only indicates exposure to a sterilization process, not sterilization adequacy.

6.1.9 For double packaging with medical paper-plastic composite, place paper-to-paper and plastic-to-plastic. Both inner and outer layers shall be sealed, with the outer layer larger. The inner layer shall be flat without folds. The internal chemical indicator shall be placed inside the inner packaging.

6.1.10 Protect sharp ends and irregular surfaces of instruments during packaging to avoid puncturing the packaging material.

6.1.11 Sealing and package closure methods shall comply with the Chinese standard WS 310.2.

6.2 Reusable Sterilization-used Packaging Materials

6.2.1 Medical Textile

6.2.1.1 The materials shall be cleaned, disinfected, and dried before first use and after each use according to product instructions. Sealing tapes shall be removed before cleaning to avoid adhesive residue.

6.2.1.2 The frequency of use shall not exceed the maximum allowed processing cycles specified in the instructions, or end-of-use criteria shall be followed per instructions.

6.2.1.3 Before each use, inspect the appearance on a lighted inspection table. Materials shall be clean, dry, odor-free, free of foreign matter and damage, without delamination, and with intact seams. Use only if it is qualified.

6.2.1.4 Select packaging methods compatible with the medical textile.

6.2.1.5 If traceability labels are used, confirm their integrity.

6.2.1.6 The stock shall match usage needs. The storage environment temperature and humidity shall comply with the product instructions.

6.2.2 Medical Rigid Sterilization Container

6.2.2.1 Follow the manufacturer's instructions.

6.2.2.2 Before the first use, conduct a sterilization efficacy test including physical, chemical, and biological monitoring, and wet pack inspection per product instructions and/or relevant requirements in the Chinese standard WS 310.

6.2.2.3 Clean, disinfect, inspect, and maintain per the Chinese standard WS 310.2 after each use.

6.2.2.4 Check structural integrity of the container; its condition for continued use shall comply with the product instructions.

6.2.2.5 Check the "closure/locking device" is intact, providing a clear indication if closure integrity is compromised.

6.2.2.6 Placement of instruments, items, etc., inside the container shall not obstruct penetration of the sterilizing agent.

6.2.2.7 Use and replacement of the container and accessories shall comply with product instructions.

6.2.2.8 The container shall be maintained regularly with records kept.